

REMARKS

In response to the Examiner's Office Action dated April 4, 2004, Applicant has clarified the language of the claims through amendments presented above, and submits that the claims define over the cited reference (Trivalent, U.S. Patent 4,246,898) for the reasons set forth below.

The present claims recite a prefilled syringe, i.e., a syringe containing "a known volume of medical fluid" (see claims 1 and 6) or a "known amount contained [in the syringe]". The prefilled syringe includes a plunger pushrod with a scale that is calibrated for the known volume that is prefilled in the syringe, i.e., there is a "scale corresponding to the known volume of the prefilled syringe" (claim 1), or "a scale calibrated to the known amount contained in the prefilled syringe". Because the amount in the syringe is known, the scale on the pushrod can be calibrated to identify the injected amount accurately.

A prefilled syringe of the kind noted, is distinctly different from a syringe that is filled by the user prior to its use, because in the latter case there is not a "known amount" in the syringe, and therefore it is not possible for the scale on the pushrod to be calibrated for a known amount.

For example, the Trivalent patent shows a syringe that is filled to any number of volumes. Although there are indicia on the Trivalent plunger, these assume a particular filled volume. As can be seen in the Trivalent patent at Fig. 1, the plunger 22 bears numerical indicia "0", "1", "2" and so on.¹ Trivalent explains that one can set the ring 56 at a desired number such as 3, and push the plunger until the ring 56 contacts the ledge 24 to inject fluid. However, in order for the numerical indicia on the plunger shaft to be meaningful, the syringe must be filled so that the "0" is positioned at the ledge 24 on the rear end of the syringe barrel 12. Only in this case, will 1 unit be injected when the ring 56 is at the "1", and so on. If the syringe is not filled to a known volume, the numerical indicia on the plunger shaft will not accurately identify an injected amount.

It will be noted that Trivalent's Fig. 1 clearly depicts a syringe that is overfilled – that is, the "0" on the plunger is not lined up with the ledge 24 but rather is extended well beyond the ledge 24. In this case, an injection performed using the ring 56 and plunger numbers will be oversize. A similar situation will occur if the syringe is

underfilled.

Applicant submits that the basic problem of accurate filling, is not dealt with by Trivalent. Indeed, Trivalent is clearly not directed to a pre-filled syringe. In fact, Trivalent's figures specifically illustrate the problem of a syringe that is filled with an uncalibrated amount of fluid.

In contrast, the present invention is directed to "pre-filled syringes" that have plunger indicia that are calibrated to a known pre-filled volume. The prior art does not show such a syringe nor suggest the use of pre-filled syringes that bear such indicia.

Applicant submits in view of the above that the claims as presented are allowable, particularly in view of the amendments submitted which clarify and amplify the "pre-filled" nature of the syringe and the calibration of the plunger indicia to a "known volume".

This response is believed to be timely filed. If any charges or credits are required to complete this communication, please apply them to Deposit Account No. 23-3000.

Respectfully submitted,

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¹ The units for these numbers are not stated and it is not apparent to Applicant what they represent.